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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,299	10/16/2001	Timothy R. Ryan	M190.137.101	7830

7590 02/11/2004

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 02/11/2004

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,299

Applicant(s)

RYAN ET AL.

Examiner

William H. Matthews (Howie)

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 30, 33 and 37-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 30, 33, and 37-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 10,11-13,15, and 37-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Myers US PN 5,716,397.

Myers discloses in figures 6B and line 46 of col. 2 through line 26 of col. 4 annuloplasty devices comprising a fabric sheath and arcuate stiffening wire disposed within the sheath having a thickness less than about 2.5 mm and eyelets disposed at the ends wherein the eyelets are marked by elements 15,62.

3. Claims 1-4,7,9-13,15,16, 30, 33, and 37-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Wright et al. US PN 5,306,296.

Wright et al. discloses in figures 2 and line 48 of col. 13 through line 66 of col. 14 annuloplasty devices comprising a fabric sheath and radiopaque arcuate stiffening wire 35 entirely disposed within the sheath having a thickness less than about 2.5 mm and ends bent back on itself to form eyelets. Markers 38 are located at the eyelets. With specific regard to claim 1, a sheath curvature length may be defined in figure 2 as slightly larger than the curvature length of the stiffening element. Figure 4B shows a stiffening element configured to independently maintain a generally saddle shape in a Z-

Art Unit: 3738

plane and arcuate in X and Y planes. Furthermore, claims 2-3 recite intended use limitations, which do not structurally limit the invention.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 5, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. US PN 5,306,296 as applied to claims 1,4,7 in the 102(b) rejection above, and further in view of Carpentier et al. US PN 5,061,277.

Wright et al. discloses an annuloplasty device meeting the structural limitations of claims 5, 6, and 8 as described above, but lacks the express disclosure of the stiffening element having the three particular radii of curvature and a silicon overmold. Carpentier et al. teaches in figures 1 and 3, lines 9-16 of col. 3, and line 57 of col. 3 through line 7 of col. 4 an annuloplasty device having a sheath and stiffening ring wherein the stiffening ring has the three particular radii of curvature (of claim 8) to properly fit the shape of the natural mitral valve, and furthermore adds a silicone overmold to make the band soft and compressible as well as more resilient.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the annuloplasty sheath and stiffening element disclosed by Wright et al. by using the particular shape and overmold taught by

Art Unit: 3738

Carpentier et al. in order to properly fit the shape of the natural mitral valve and make the band soft and compressible as well as more resilient.

6. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. US PN 5,306,296 as applied to claim 1 in the 102(b) rejection above, and further in view of Loch et al. US PN 6,174,332.

Wright et al. or Myers discloses an annuloplasty device meeting the structural limitations of claim 14 as described above, but lacks the express disclosure of the sheath being formed of biological tissue. Loch et al. teaches in lines 44-57 of col. 3 an annuloplasty ring having a sheath made of biological tissue to provide sufficient biocompatibility.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the annuloplasty sheath disclosed by Wright et al. or Myers by using biological tissue as taught by Loch et al. in order to provide sufficient biocompatibility.

Conclusion

7. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued

Art Unit: 3738

examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Application/Control Number: 09/982,299


Page 6

Art Unit: 3738

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February 6, 2003


David H. Willse
Primary Examiner